UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA *et al.* *ex rel.* JULIE LONG, Plaintiffs, v. JANSSEN BIOTECH, INC., Defendant.	)	Civil Action No. 16-CV-12182-FDS

RELATOR'S MEMORANDUM OF LAW IN OPPOSITION TO
DEFENDANT'S MOTION TO COMPEL

Table of Contents

I. Relator Conferred With Janssen On Multiple Occasions And Already Supplemented An Interrogatory Response To Ensure That It Understands The Remuneration/Kickbacks At The Center Of This Action, And She Did Not Refuse To Participate In A Pre-Motion Telephone Meeting 1

II. Janssen's Contention That Relator Should Be Required To Amend Her Interrogatory Responses To Correct An Inconsistency Is Baseless Because There Is No Inconsistency To Correct 2

A. The conduct at the center of this action is not the provision of written materials to doctors, as Janssen keeps trying to have the Court believe; rather, it is the free practice management and infusion business advisory services and support that Janssen had its special team of Area Business Specialists and outside consultants regularly provide to targeted physician practices through live consultative meetings 3

B. Relator's interrogatory responses clearly and accurately describe the remuneration/ kickbacks underlying Relator's AKS and FCA claims 5

C. Relator's arguments opposing Janssen's motion contending that it should be granted immunity from Relator's claims under the FCA's public disclosure provision are accurate and entirely consistent with her allegations and interrogatory responses 14

III. Conclusion 16

Plaintiff-relator Julie Long ("Relator") submits this memorandum of law in opposition to defendant Janssen Biotech's motion requesting that the Court require Relator to amend her interrogatory responses.

Janssen's motion has no merit and is nothing more than a veiled attempt to distort Relator's allegations and create the false impression that the alleged remuneration/kickbacks underlying Relator's Anti-Kickback Statute ("AKS") and False Claims Act ("FCA") claims are written materials, not the free live consultative services and support that Janssen had its Area Business Specialists and outside consultants regularly provide to targeted physician practices over an extended period to help them open and subsequently operate infusion suites in their offices, as Relator clearly alleges in her complaint and describes in her response to Interrogatory 2. Because the description in Relator's interrogatory responses of the remuneration/kickbacks that are at the center of this case is clear, accurate, and entirely consistent with the arguments she made to the Court describing the alleged remuneration/kickbacks, there is no ambiguity or inaccuracy to correct, and this motion should be denied.

I. Relator Conferred With Janssen On Multiple Occasions And Already Supplemented An Interrogatory Response To Ensure That It Understands The Remuneration/ Kickbacks At The Center Of This Action, And She Did Not Refuse To Participate In A Pre-Motion Telephone Meeting

As evidenced by the email correspondence Janssen submitted with this motion, *see* ECF 399-7, as well as a related email that Janssen failed to provide with its motion, *see* May 26, 2023 email from Casey Preston to Matthew Dunn (a copy is provided herewith as Exhibit 1 (ECF 400-1 at 3-4), Relator conferred with Janssen on multiple occasions trying to address its repeated mischaracterizations of Relator's allegations. And even though Janssen's assertions lack merit, Relator nonetheless supplemented her response to Interrogatory 2 to make her description of the alleged remuneration/kickbacks underlying her AKS and FCA claims, the only claims asserted in

this action, even more precise. But even after Relator supplemented her response to Interrogatory 2, Janssen continued misreading and mischaracterizing Relator's allegations and falsely contending that her response to Interrogatory 2 is inconsistent with other interrogatory responses and an argument she made to the Court distinguishing the act of providing a document to all physicians, conduct reported in *In re Pharmaceutical Industry Average Wholesale Price ("AWP") Litigation*, No.01-12257-PBS (D. Mass.) ("*AWP Class Action*"), a case filed more than 20 years ago that did not involve AKS violations, from the conduct underlying the claims in this action. Relator subsequently conferred again with Janssen concerning its continued false contentions, reiterating the reasons why its characterizations of the allegations were inaccurate. And, as also evidenced by the correspondence Janssen submitted with this motion, when Janssen subsequently asked Relator to participate in a pre-motion telephone conference, Relator did not refuse. Not seeing an actual issue or dispute that could be raised with the Court, Relator asked Janssen to explain the dispute it was considering raising so that she could be prepared for the telephone meeting and, if appropriate, address the issue before the meeting. *See* July 11, 2023 emails from C. Preston to M. Dunn (ECF 399-7) at 2-3. Janssen, however, would not specify the dispute or relief it planned to seek. A month later, Janssen filed this motion incorrectly reporting to the Court that Relator refused to meet and confer concerning the purported issue raised in the motion, which for the reasons stated below lacks any merit.

II. Janssen's Contention That Relator Should Be Required To Amend Her Interrogatory Responses To Correct An Inconsistency Is Baseless Because There Is No Inconsistency To Correct

This motion asking the Court to require Relator to change her interrogatory responses is predicated on an alleged inconsistency between Relator's answers to interrogatories that describe the remuneration/kickbacks underlying the alleged AKS and FCA violations in this action and

arguments Relator made in opposing Janssen's pending motion for judgement on the pleadings in which it asserts that it is immune from this action under the FCA's public disclosure provision (ECF 377). The contention that an inconsistency exists is pure sophistry, as it is grounded on a misreading and mischaracterization of Relator's allegations and interrogatory responses, and Janssen fails to cite to any actual allegation or statement in which Relator stated that her AKS and FCA claims are based on the act of giving physicians "written presentations" or any other written materials. As demonstrated below, Relator's description of the services underlying her AKS and FCA claims in her interrogatory responses, which Relator has already supplemented and made even more precise as result of Janssen's baseless assertions, is clear and accurate and in no way conflicts with the arguments she made in opposing Janssen's meritless public disclosure motion. Because there is no inconsistency that would necessitate Relator to amend her interrogatory responses or her briefing, this motion should be denied.

A. The conduct at the center of this action is not the provision of written materials to doctors, as Janssen keeps trying to have the Court believe; rather, it is the free practice management and infusion business advisory services and support that Janssen had its special team of Area Business Specialists and outside consultants regularly provide to targeted physician practices through live consultative meetings

Relator is pursuing this qui tam action on behalf of the United States ("Government") to hold Janssen accountable for the significant damages it has caused to Medicare and its beneficiaries by engaging in a scheme through which it provided valuable business advisory services to select physician practices for free to induce them to prescribe two of its drugs to patients. Since the early 2000s, one of Janssen's main strategies for growing sales of Remicade and Simponi ARIA—two drugs administered by infusion—was to promote the infusion business model by helping rheumatology and gastroenterology practices open an in-office infusion suite ("IOI") and, after the IOI was open, by influencing the physician practices to perform more

infusion procedures. As part of this strategy, Janssen employed a large team of business advisers to regularly furnish operational support and essentially serve as business partners to doctors who committed to the infusion business model and operated IOIs. *See* Second Am. Compl. ("SAC") (ECF 55) at ¶122. Janssen called this special team of employees "Area Business Specialists," or "ABSs" for short, and advised physician practices that the business support and services the ABSs provided were free of charge. *See id*. Each Remicade and Simponi ARIA sales territory had an ABS in addition to the customary sales representatives and medical science liaisons. *See id.* at ¶¶124-25. Relator was an ABS from 2003 to 2016. *See id.* at ¶16. Janssen also paid outside consultants with expertise in practice management and infusion suite management, such as Xcenda, to assist doctors with opening and operating IOIs. *See id.* at ¶¶123, 135.

Janssen had ABSs and outside consultants meet with physician practices that did not have an IOI and advise them to open an IOI to perform infusions in their offices. *See id.* at ¶¶120-21. Janssen then advised doctors who were interested in opening an IOI on how to do so and assisted them with getting it up and running. *See id.* at ¶¶139-44. Once open, Janssen wanted to make sure the physicians kept the IOIs open and grew the number of infusion procedures they performed, especially of Janssen's drugs. *See id.* at ¶¶145-65. To accomplish this, Janssen had ABSs and outside consultants regularly provide the physician practices free practice management and infusion business advice and support on a wide range of topics that are enumerated in Relator's response to Interrogatory 2 (collectively, the "Services"), as discussed in more detail below. *See id.* at ¶166. Most of these Services were delivered through live consultative meetings that were also commonly referred to as "presentations" and "programs," which, as discussed below, are specifically identified in Relator's response to Interrogatory 2. The free Services and the live presentations and programs through which the Services were

furnished are collectively referred to herein as the "IOI Support."

The IOI Support, which was regularly provided to targeted physician practices over several years and helped doctors open, operate, and grow their IOIs, where they infused a variety of infusible drugs, not just Remicade and Simponi ARIA, provided broad value to the physicians. *See id.* at ¶¶8, 165-66, 173, 177-85. Although the IOI Support applied to the overall infusion business and all infusible drugs, Janssen's purpose in providing it was to influence doctors' treatment decisions and induce prescriptions of Remicade and Simponi ARIA to their patients, including Medicare beneficiaries. *See id.* at ¶¶186-88.

By providing this illegal remuneration to induce prescriptions to Medicare beneficiaries, which Relator alleges Janssen knew was unlawful, Janssen violated the AKS. The claims for reimbursement for Remicade and Simponi ARIA submitted to Medicare on or after October 28, 2010, by doctors after receiving the alleged illegal remuneration/kickbacks are false claims under the FCA. By causing these false claims, Janssen violated 31 U.S.C. §§ 3729(a)(1)(A) and (B).

Thus, as her complaint, her interrogatory responses, her substantial briefing submitted in this action, and her counsel's correspondence all explicitly state: ***the alleged remuneration upon which Relator's AKS and FCA claims are based is the free live Services and consultative presentations and programs through which the ABSs and outside consultants provided the Services (collectively the IOI Support)***. To be clear, Relator is not alleging AKS and FCA violations predicated on any other conduct, such as giving written materials to doctors or paying them cash and disguising it as preceptorship fees, as Janssen has falsely contended in an effort to confuse matters and distract the Court's attention away from the real allegations and issues.

B. Relator's interrogatory responses clearly and accurately describe the remuneration/kickbacks underlying Relator's AKS and FCA claims

As part of its effort to fabricate an inconsistency and have the Court believe that the

alleged remuneration in this case includes written materials similar to a document from the *AWP Class Action* that Janssen's predecessor allegedly provided to all doctors to market the reimbursement spread that could be earned on Remicade, an entirely different scheme from the AKS and FCA violations at issue here, Janssen seeks to create the false impression that the "presentations" described in Relator's interrogatory responses are "written presentations." However, Janssen's assertion disregards Relator's response to Interrogatory 2—as well as her complaint, briefing, and correspondence—in which she specifies that the remuneration/ kickbacks underlying her AKS and FCA claims are the Services listed in the response and the consultative presentations and programs specified in the response that were provided in-person, by teleconference, or by videoconference (not simply via a document, if that is even possible) through which Janssen's ABSs and outside consultants provided the Services.

Showing it understands that this action is focused on the Services that Janssen regularly provided to targeted physician practices to induce prescriptions of Remicade and Simponi ARIA to Medicare beneficiaries, Janssen propounded Interrogatory 2, asking Relator to identify the particular "services" that she alleges violated the AKS. *See* Pl.'s Resp. to Interrog. 2 (ECF 399-1) at 7. In her response, which she has supplemented to reflect information obtained in discovery and to make even more precise due to Janssen's mischaracterizations, Relator specifies the conduct underlying her AKS and FCA claims. Specifically, her response states, in relevant part:

> Advisory, educational, and consultative assistance, support, and services concerning the topics listed below (hereinafter, collectively referred to as the "Services") that Defendant provided (directly through Area Business Specialists or through outside consultants (such as Xcenda, The Lash Group, The Resource Group, and Akin Gump)), under national directives, to the [focus accounts in Relator's former territory in Pennsylvania] as well as other selected or targeted physician practices that are identified in documents Defendant produced constituted illegal remuneration, the provision of which violated the Anti-Kickback Statute:
>
> (1) establishing and opening an initial IOI (defined below)
>
> (2) opening an IOI at another location

(3) the practice's readiness for administering infusions in a new IOI

(4) the optimal design, furniture, and décor of the IOI

(5) using a gastroenterology practice's ambulatory surgical center as an IOI (reclassifying ASC space to office space to allow for provision of infusion services in compliance with Medicare requirements)

(6) identifying and addressing a practice's IOI's operational needs and challenges

(7) enhancements to the IOI that would increase patient satisfaction (to attract more patients and enable the practices to negotiate higher reimbursement rates from private payers and patients)

(8) the infusion business model

(9) growing or maintaining the IOI

(10) the assessment and evaluation of the IOI's infusion procedure volume and capacity

(11) adding other infusion service lines or treatments to an IOI

(12) making other physicians, who do not perform infusions in their offices, aware of the practice's IOI and seeking referral arrangements with such physicians

(13) operating IOIs more efficiently and profitably (and lowering overhead costs)

(14) optimizing the infusion schedule (maximizing infusion procedures and minimizing staffing time and costs)

(15) establishing and implementing standard operating procedures to improve the IOI workflow and billing processes

(16) management of the inventory of infusible drugs and infusion procedure supplies

(17) acquisition of drugs administered in the IOI

(18) management of the financial risks related to infusing drugs in the IOI

(19) tracking accounts receivable and payments from payers and patients for infusion drugs and services

(20) obtaining coverage exceptions and overturning payment denials through appeals

(21) private payer coverage and reimbursement trends

(22) best contracting practices and management of relationships with private payers and the government health care programs

(23) negotiating higher reimbursement rates from private payers for frequently billed services and drugs (starting with benchmarking and evaluating existing terms of contracts with private payers and reimbursement rates)

(24) government legislative and policy changes, programs, and trends that impact physician practices

(25) avoiding and responding to an audit of the practice's claims for payment by Medicare

(26) qualifying for incentive payments and avoiding penalties under the Health Information Technology for Economic and Clinical Health (HITECH) Act and Medicare's Electronic Health Record Incentive Program (including achieving meaningful use criteria with electronic health records)

(27) qualifying for incentive payments under Medicare's Electronic-Prescribing (eRx) Incentive Program

(28) qualifying for the incentive payments and payment adjustments under CMS's Physician Quality Reporting System (PQRS)

(29) qualifying for the incentive payments under Medicare's Merit-Based Incentive Payment System

(30) preparing the practice for conversion to the ICD-10 coding system

Id. at 8-10. As she did in her complaint (*see* SAC at ¶166), in her response to Interrogatory 2, Relator also describes how Janssen's ABSs and outside consultants delivered most of the above Services to the targeted physician practices through regular live consultative meetings, listing the specific names that Janssen assigned to the consultative meetings:

> With the exception of advice and assistance provided concerning opening an initial IOI and opening an IOI at another location (items 1-3 above), the Services listed above were normally provided to the selected and targeted practices through consultative meetings, which were also commonly referred to as, among other names, "programs" and "presentations," that were presented by Area Business Specialists (in-person) or by outside consultants (in-person, by teleconference, or by videoconference) (hereinafter, the "presentations and programs"), including the presentations and programs identified below (and their substantive equivalents):
>
> (1) Becoming an Alternative Site of Care for Therapy with Remicade in Your Community
>
> (2) Billing and Coding for Infusions
>
> (3) Checkpoints for Infusion Center Optimization
>
> (4) Considerations for Proactive Practice Management (a/k/a Current Considerations for Proactive Practice Management; Proactive Practice Management)
>
> (5) Considerations for Standard Operating Procedures in the Infusion Suite
>
> (6) Considerations for Working with a Specialty Pharmacy (a/k/a Specialty Pharmacy Considerations)
>
> (7) Electronic Health Records and Meaningful Use (Part 1 and Part 2)
>
> (8) Emerging Trends in Health Care
>
> (9) Enhancing Patient Care and Access
>
> (10) Exceptions and Appeals

(11) ICD-10

(12) In-Office Infusion Drug Procurement Models

(13) Infusion Business Review (a/k/a iBiz)

(14) Infusion Optimization Modeler (a/k/a IOM)

(15) Infusion Referrals: Improving the Continuity of Care (a/k/a Coordinating the Continuity of Care with Infusion Referrals; Quality Improvements in Coordinating the Continuity of Care with Infusion Referrals)

(16) Infusion Services Review

(17) Infusion Suite Scheduling and Staffing

(18) Infusion Therapy Services Provided in Converted ASC Space (a/k/a Infusion Services and Ambulatory Surgical Centers (ASCs) – Planning Considerations; ASC Space Reclassification for Infusion Therapy)

(19) Inventory and Supply Management

(20) IV Therapy: An Important Option for Your Patients (a/k/a Why IV)

(21) Managing Biologics in the Physician Office (a/k/a MBPO)

(22) Medicare Audits

(23) *Medicare Quality Payment Program: A Focus on MIPS

(24) *Patient Experience in the Infusion Suite

(25) Payer Relationship Management

(26) Practice Compliance for Remicade

(27) Private Payer Contracting Considerations (Part 1 and Part 2) (a/k/a Private Payer Contracting Considerations for Therapy with Remicade)

(28) Quality of Care in the Infusion Suite

(30) Raising the Infusion Suite Experience (a/k/a RISE)

(31) Remicade Account Review (a/k/a Physician Office Account Review for Remicade)

(32) Setting Up In-Office Infusions of Remicade: Informational Resources

(33) *Specialty Drug Market Dynamics: Implications for Infusions

(34) Successful Implementation of a New Infusion Suite

(35) Successful Implementation of a New Infusion Suite for Gastroenterology Practices

(36) Successful Infusion Site Management for Gastroenterology (a/k/a Successful Infusion Suite Management for Gastroenterology)

(37) Akin Gump teleconferences, including, but not limited to: (a) Medicare Physician Payment Update; (b) Healthcare Reform Update; and (c) Medicare Shared Savings Program and Accountable Care Organization Proposed Rule Update

Id. at 10-12.

Significant to this motion, even though Janssen understands that it commonly referred to the regularly conducted live consultative meetings through which its ABSs and outside consultants provided many of the Services as "presentations" and "programs," to ensure Janssen could not feign that it does not know what "presentations" and "programs" refers to, Relator specifically instructed in her response to Interrogatory 2 that:

> [T]he Services listed above were normally provided to the selected and targeted practices through ***consultative meetings, which were also commonly referred to as, among other names, "programs" and "presentations," that were presented by Area Business Specialists (in-person) or by outside consultants (in-person, by teleconference, or by videoconference) (hereinafter, the "presentations and programs")***, including the presentations and programs identified [in Relator's Response to Interrogatory 2].

Id. at 10 (emphasis added). And so, it was made explicit to Janssen that "presentations" and "programs," as used in her interrogatory responses and the case, mean the live consultative meetings through which ABSs and outside consultants provided the Services.[1] Similarly, Relator also made this explicit to Janssen in correspondence sent before supplementing her response to Interrogatory 2, which the company failed to share with the Court:

> [W]e write to respond to the letter that you emailed yesterday. The statements in your letter reflect a disregard of the allegations in Relator's complaint, a lack of familiarity with terms Janssen used, and a misreading of Relator's interrogatory responses.
>
> As Relator's complaint, motion to dismiss briefing, and interrogatory responses make clear, ***the illegal remuneration at issue are the consultative services and support that Janssen provided, through Area Business Specialists and outside consultants, such as Xcenda, concerning various practice management and IOI business and operational topics that had substantial independent value and that were provided to select and targeted physician practices for free. The evidence shows, and Janssen knows, that Janssen and its ABSs often referred to the sessions or meetings during which the***

[1] Similarly, because Relator has used the terms "Infusion Business Support" and "IOI Support" during this litigation, including in this brief, to collectively refer to the Services and the related presentations and programs through which many of the Services were provided, Relator also made it clear in her response to Interrogatory 2 that "Infusion Business Support" and "IOI Support" refer to "the Services and the related presentations and programs through which Services were provided." *See* Pl.'s Resp. to Interrog. 2 (ECF 399-1) at 10 n.1.

> ***consultative services and support were provided, including the slide decks, optimization models, and other materials utilized in the sessions or meetings, as "programs" and "presentations," as well as other names.*** And, as the evidence shows, and Janssen knows, the slide decks, optimization models, and other materials presented and discussed during the consultative and IOI business advisory meetings/ sessions/programs /presentations were utilized by the ABSs and outside consultants as part of and to facilitate the delivery of consultative services and support.
>
> Although it is clear from Relator's complaint, briefing, and interrogatory responses, ***Relator reiterates that she is not asserting a claim based on Janssen merely providing or making available to all providers a guide, brochure, or pamphlet, such as it appears to have done with the July 1999 Office-Based Infusion Guide that you relied upon in your motion.***
>
> In the event that you are asserting that the ABSs and outside consultants did not provide consultative services and support through meetings/sessions/programs/presentations but rather merely handed out the slide decks to physician practices, that those slide decks were provided to all physician practices, and/or that the slide decks were made available to all providers on Janssen's website, such assertion is incorrect, as that is not what the Relator did or witnessed and is not supported by the evidence. In fact, as you know, the ABSs were not even permitted to leave a copy of the slide decks with the select physician practices who received the free consultative services. If Janssen possesses evidence that you believe supports your assertions, please provide it.
>
> While Relator has clearly identified the consultative services and support that she alleges constituted illegal remuneration and has likewise clearly identified the consultative sessions/programs/presentations through which the services and support were furnished by Janssen, Relator will be refining her answer to Interrogatory 2 and in doing so will again make clear that ***the illegal remuneration in this case consists of the free practice management and infusion business advisory services and support that Janssen, through the ABSs and outside consultants, provided to select and targeted physician practices during consultative meetings and sessions, that were also commonly referred to as programs and presentations.***

May 26, 2023 email from C. Preston to M. Dunn - Ex.1 (ECF 400-1) at 3-4 (emphasis added); *accord* June 29, 2023 email from C. Preston to M. Dunn (ECF 399-7) at 8.

In her answer to Interrogatory 2, Relator specifically described how ABSs and outside consultants often used visual aids, such as slide decks, during the live presentations and programs: "As part of the presentations and programs, Defendant typically had the Area Business Specialists and outside consultants use slide decks as visual aids (presented on the Area

Business Specialist's electronic device or projected on a screen) and, for some presentations and programs, customized infusion schedule optimization models and other materials to assist with and facilitate the provision of the Services." *Id.* While Relator's response to Interrogatory 2 explains that slide decks and other visual aids were often a component of the live presentations and programs through which the ABSs and outside consultants provided the Services, Relator does not allege that the slide decks and other visual aids themselves were the Services or presentations that constitute the remuneration/kickbacks, as Janssen falsely portrays. Indeed, nowhere in her highly specific response to Interrogatory 2, nor anywhere else, does Relator state that her AKS and FCA claims are based on conduct that consisted of merely giving physicians written materials, whether it be a slide deck or guide containing information about starting an IOI. Janssen does not and cannot point to such an allegation.

Relator has no knowledge that Janssen did this, but assuming arguendo the drug company handed out a copy of an IOI operations manual to every rheumatology and gastroenterology practice during the relevant period for this discovery phase (October 2010 to February 2016), that conduct would not be included within Relator's AKS and FCA claims because it would have been fundamentally different from the conduct and scheme Relator alleges – *i.e.*, providing regular, live practice management and infusion business advisory services by ABSs and outside consultants to targeted physician practices free of charge. Here again, Relator is not expressing a view on whether providing such an item would constitute a violation of the AKS, she is simply using this hypothetical to highlight the stark contrast between the conduct underlying her AKS and FCA claims and the act of making written materials available to all physicians, as Janssen's predecessor allegedly did in disseminating the Guide referenced in the *AWP Class Action*.

In light of the clear explanation provided in the response to Interrogatory 2, the meaning

of "services," "presentations," and "programs" in Relator's responses to other interrogatories is likewise clear and in no way inconsistent with the response to Interrogatory 2. For instance, in Interrogatory 12, Janssen asked Relator to identify all the false claims for reimbursement for Remicade and Simponi ARIA that she alleges Janssen caused the focus physician practices from her former territory to submit to Medicare. *See* Pl.'s Resp. to Interrog. 12 (ECF 399-3) at 20-21. Clearly, accurately, and consistent with her response to Interrogatory 2 and complaint, Relator explains in her response to Interrogatory 12 that:

> Plaintiff alleges that all claims for payment for Remicade, Simponi ARIA, and related infusion procedures that health care providers associated with the Phase 1 Accounts submitted to Medicare on or after October 28, 2010 and after the Phase 1 Account received one or more of the services, presentations, or programs identified in Plaintiff's response to Interrogatory 2 constitute claims that were false or fraudulent in violation of 31 U.S.C. § 3729(a)(1)(A) & (B).

Id. at 20. Thus, the alleged remuneration/kickbacks described in the response to Interrogatory 12 are similarly cabined to the defined Services and the consultative presentations and programs through which many of the Services were delivered. Yet again, contrary to Janssen's assertions, Relator does not state that a claim for reimbursement was rendered false because the physician practices were provided written materials or a written presentation.

Relator's interrogatory responses accurately describe the remuneration/kickbacks underlying her AKS and FCA violations. And despite Janssen's assertions, Relator is not required to identify in her responses hypothetical conduct that would fall outside the well-defined scope of the remuneration/kickbacks that she alleges. Similarly, despite Janssen's assertions, Relator is not required to answer Janssen's inquiries on whether conduct that she does not allege occurred might constitute a violation of the AKS.

C. Relator's arguments opposing Janssen's motion contending that it should be granted immunity from Relator's claims under the FCA's public disclosure provision are accurate and entirely consistent with her allegations and interrogatory responses

In support of its motion for judgment on the pleadings pending before the Court (ECF 377), which lacks merit and should be denied for the reasons Relator stated in her briefing and during oral argument, Janssen contended that the Government would have already been aware of the AKS and FCA violations Relator alleges in this action from information and allegations that it unearthed and strung together from three much earlier lawsuits. Included in the allegations and information Janssen assembled to manufacture its public disclosure argument were allegations and information from the *AWP Class Action* filed in 2001. In the *AWP Class Action*, the plaintiff class sought to redress overcharges that they claimed to have wrongfully paid as a result of Janssen's predecessor Centocor's alleged practice of reporting inflated pricing for Remicade and marketing the reimbursement spread to physicians, a different scheme than the kickback scheme through which Janssen defrauded the Government that Relator alleges in this action.

In support of its public disclosure argument, Janssen contends that a document produced in the *AWP Class Action* titled "Office-Based Infusion Guide" and dated July 1999 (the "Guide") that Centocor allegedly made available to all physicians on its website[2], in combination with other snippets of information from that case and the two other earlier cases, would have put the

[2] The plaintiff class in the *AWP Class Action* alleged, in relevant part, that:

> The J&J Group created promotional materials and worksheets to allow them to market the spread between the published AWP and the actual selling price to doctors. For example, a publication accessible through Defendants' web sites entitled "Office-Based Infusion Guide" demonstrates Defendants' aggressive marketing of this spread, specifically noting that, "[d]epending on reimbursement, office-based infusion may provide a financial impact to a physician's practice." …

3d Am. Consol. Class Action Compl. in the *AWP Class Action* at ¶453 (Ex.D to Def.'s Mot. for J. on the Pleadings (ECF 378-5)).

Government on notice that Janssen was engaged in the fraud that Relator alleges. In her briefing opposing Janssen's motion for judgment on the pleadings, Relator argued that the allegations and information from the *AWP Class Action* concerning the Guide do not constitute a public disclosure for purposes of the FCA. In addition to other arguments[3], Relator distinguished the act of making the Guide available to all physicians by publishing it on a website from the very different act of having ABSs and outside consultants provide targeted physician practices with the live consultative Services at issue here. *See* Pl.'s Brf. In Opp. (ECF 381) at 20-21; Pl.'s Sur-Reply (ECF 389) at 7. As demonstrated above, this argument is accurate and consistent with the allegations in Relator's complaint and the description of the remuneration underlying her AKS and FCA claims in her responses to Interrogatories 2 and 12.

Moreover, Janssen's contention that its use of slide decks during the live presentations and programs through which it provided the Services is no different than Centocor making the Guide available to physicians is way off the mark. Both the conduct and the written materials were fundamentally different. The slide decks were used by the ABSs and outside consultants during live consultative presentations to facilitate the provision of the Services to targeted physician practices. On the other hand, based on the information and allegations from the *AWP Class Action*, the Guide was provided or made available to all physicians via Centocor's website

[3] Relator also argued that the allegations and information concerning the Guide cannot constitute a public disclosure under the FCA because the *AWP Class Action* was not a Federal hearing in which the Government or its agent was a party, as the FCA's public disclosure provision (31 U.S.C. § 3730(e)(4)(A)) requires. *See* Pl.'s Brf. in Opp. (ECF 381) at 12-14; Pl.'s Sur-Reply (ECF 389) at 5-7. Additionally, Relator argued that the allegations and information regarding the Guide would not have disclosed the fraud Relator alleges to the Government, as they did not report that Centocor was providing, free of charge, live consultative meetings through which ABSs or outside consultants provided practice management and business advisory services on a wide variety of topics and issues to targeted physician practices on a regular basis. *See* Pl.'s Brf. in Opp. (ECF 381) at 21-22; Pl.'s Sur-Reply (ECF 389) at 9.

and was not a visual aid designed for use during a live consultative program provided by ABSs and outside consultants to select physician practices. The act of providing an item, such as a document, or even a textbook, to all physicians, whether by handing it to them or making it available on the company's website, is profoundly different conduct than having business advisers and consultants with subject matter expertise provide the consultative Services/IOI Support to targeted physician practices. And, unlike the Guide referenced in the *AWP Class Action*, the slide decks and visual aids that were utilized during the consultative presentations and programs at issue in this case were not made available to everyone on a website or handed out to physicians like pamphlets. To the contrary, as Relator alleges (*see* SAC at ¶170), the ABSs and outside consultants normally were not permitted to leave the slide decks behind with the targeted physician practices after providing the live consultative presentations and programs.

Additionally, the slide decks utilized during the consultative presentations that ABSs and outside consultants provided contained far more information and detail than the Guide and addressed a much broader variety of practice management and infusion business issues. Some of the visual aids incorporated customized analyses allowing the ABSs to help better address the recipient physician practice's specific needs and issues. It should be noted that even though slide decks were used in most, if not all, of the 37 presentations and programs listed in the response to Interrogatory 2, Janssen tellingly submitted just one of the slide decks with its motion.

As demonstrated herein, Relator's arguments distinguishing the Guide referenced in the *AWP Class Action* from the remuneration/kickbacks at issue in this case are accurate.

III. Conclusion

Because Relator's responses to Janssen's interrogatories clearly and accurately describe the remuneration/kickbacks on which her AKS and FCA claims are based, and there is no

inconsistency between her allegations and the arguments that she made in opposing Janssen's motion for judgment on the pleadings, there is no ambiguity or inaccuracy to address. The Court should deny this motion that seeks to force Relator to again supplement or change her interrogatory responses in order to address assertions made by Janssen that are false.

Dated: August 23, 2023

Respectfully submitted,

/s/ Casey M. Preston
Casey M. Preston (admitted pro hac vice)
Gary L. Azorsky (admitted pro hac vice)
Jeanne A. Markey (admitted pro hac vice)
COHEN MILSTEIN SELLERS & TOLL PLLC
100 N. 18th Street, Suite 1820
Philadelphia, PA 19103
(267) 479-5700
cpreston@cohenmilstein.com
gazorsky@cohenmilstein.com
jmarkey@cohenmilstein.com

Theodore J. Leopold (admitted pro hac vice)
Leslie M. Kroeger (admitted pro hac vice)
Diana L. Martin (admitted pro hac vice)
Poorad Razavi (admitted pro hac vice)
COHEN MILSTEIN SELLERS & TOLL PLLC
11780 U.S. Highway One, Suite N500
Palm Beach Gardens, FL 33408
(561) 515-1400
tleopold@cohenmilstein.com
lkroeger@cohenmilstein.com
dmartin@cohenmilstein.com
prazavi@cohenmilstein.com

Jonathan Shapiro (BBO No. 454220)
SHAPIRO & TEITELBAUM LLP
90 Canal Street, Suite 120
Boston, MA 02116
(617) 742-5800
jshapiro@jsmtlegal.com

Counsel for Plaintiff-Relator Julie Long

Certificate of Service

I hereby certify on this 23rd day of August, 2023, that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/ Casey M. Preston
Casey M. Preston (admitted pro hac vice)